



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,156	12/21/2001	Roger A. Sabbadini	078853-0304	4039

30542 7590 11/12/2003

FOLEY & LARDNER
P.O. BOX 80278
SAN DIEGO, CA 92138-0278

EXAMINER

TURNER, SHARON L

ART UNIT	PAPER NUMBER
----------	--------------

1647

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,156	SABBADINI, ROGER A.	
	Examiner	Art Unit	
	Sharon L. Turner	1647	

-- Th MAILING DATE of this communication appears on th cover sh et with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restriction

1. Claims 1-20 are pending.

Improper Markush

2. Prior to setting forth the restriction requirement, it is pointed out that applicants have presented instant claims in improper Markush format, see *Ex parte Markush*, 1925 C.D. 126, *In re Weber*, 198 USPQ 334 and MPEP 803.02 and 806.04. The claims are improperly set forth as the genus claims encompassing multiple products, as identified and claimed, fail to share the characteristics of a genus, i.e., a common utility and a substantial structural feature essential to the disclosed utility. Alternatively, the claims define multiple structurally distinct compounds capable of different use, with different modes of operation, different function and different effects. A reference against one of the claimed components or methods would not be a reference against the other. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims define inventions which are not proper species.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12 in part drawn respectively to a method for treating or preventing comprising administering an agent that binds a sphingolipid or sphingolipid metabolite, classified for example in class 514, subclass 2.

- II. Claims 13-20 in part drawn respectively to a method for treating or preventing comprising administering an agent that binds a sphingolipid receptor or sphingolipid receptor metabolite, classified for example in class 514, subclass 2.

4. The inventions are distinct, each from the other because of the following reasons:

5. Inventions I-II are related as processes. The processes are distinct each from the other as the processes differ in reagents, steps, functions and effects.

6. Furthermore, in addition to the election of one of the above VIII groups, further restriction is required under 35 U.S.C. 121 as set forth below to delineate the molecular embodiments to which the claims will be restricted in accordance with the elected group:

Regardless of Group, a single designated agent should be elected from a) antibody, b) a non-catalytic derivative of an enzyme, c) a soluble fragment of a receptor, SEQ ID Nos: 1, 3-8 and 9.

In addition, if Group I is elected, applicant should elect a single sphingolipid selected from a) sphingomyelin, b) sphingosine, c) S-1-P, d) ceramide, e) SPC, f) 3-ketosphinganine, g) galactosylceramide and dihydroceramide.

In addition, if Group II is elected, applicant should elect a single sphingolipid receptor selected from Edg-1, Edg-3, Edg-5, Edg-6, Edg-8, Mil, AXOR29, NRG1, SCaMPER, SEQ ID NO:7, SCaMPER encoded by SEQ ID NO:3 and SCaMPER encoded by SEQ ID NO:4.

7. The inventions are distinct, each from the other because of the following reasons:

8. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because the products indicated constitute patentably distinct inventions for the following reasons. Each of the agents, sphingolipids and receptors has a unique structural feature which requires a unique search of the prior art. The inventions indicated differ in structure and function as they are composed of divergent amino acids and are differentially able to bind or mediate biological functions. A reference to one element would not constitute a

Art Unit: 1647

reference to another. In addition, searching all of the molecules in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because the indicated searches are not co-extensive.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

10. Because these inventions are distinct for the reasons given above and the search required for any Group is not required for any other Group, restriction for examination purposes as indicated is proper.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated groups I-II and a single molecular embodiment for each of the designated groups to which the claims will be restricted, even though the requirement is traversed. Applicant is advised that neither I-II, the agent, sphingolipid nor receptor are species election requirements; rather each of I-II, the agent, sphingolipid and receptor are restriction requirements. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

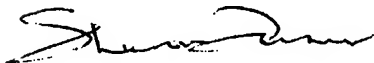
Art Unit: 1647

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.



Sharon L. Turner, Ph.D.
November 10, 2003